

WHAT IS CLAIMED IS:

1           1.    A method for aerosolizing a dose of insulin,  
2    said method comprising:  
3            providing insulin as a dry powder;  
4            dispersing an amount of the dry powder in a gas  
5    stream to form an aerosol; and  
6            capturing the aerosol in a chamber having a  
7    mouthpiece for subsequent inhalation by a patient.

1           2.    A method as in claim 1, wherein the insulin is  
2    substantially free from penetration enhancers.

1           3.    A method as in claim 1, wherein the insulin is  
2    present in a dry powder carrier at a weight concentration in  
3    the range from about 5% to 99%.

1           4.    A method as in claim 3, wherein the powder  
2    carrier comprises a carbohydrate, organic salt, amino acid,  
3    peptide, or protein.

1           5.    A method as in claim 1, wherein the insulin dry  
2    powder comprises particles having an average size below 10  $\mu\text{m}$ .

1           6.    A method as in claim 1, wherein the dry powder  
2    comprises individual particles including both insulin and a  
3    carrier material.

1           7.    A method a in claim 6, wherein the insulin is  
2    present in the individual particles at from 5% to 99% by  
3    weight.

1           8.    An improved method for the respiratory delivery  
2    of insulin, wherein the improvement comprises delivering the  
3    insulin as a dry powder.

1           9.    An improved method as in claim 8, wherein the  
2    insulin is substantially free from penetration enhancers.

1           10. An improved method as in claim 8, wherein the  
2 insulin is present in a dry powder carrier at a weight  
3 concentration in the range from about 10% to 99%.

1           11. An improved method as in claim 10, wherein the  
2 powder carrier comprises a carbohydrate, organic salt, amino  
3 acid, peptide, or protein.

1           12. An improved method as in claim 8, wherein the  
2 insulin dry powder comprises particles having an average size  
3 below 10  $\mu\text{m}$ .

1           13. An improved method as in claim 8, wherein the  
2 dry powder comprises individual particles including both  
3 insulin and a carrier material.

1           14. An improved method as in claim 13, wherein the  
2 insulin is present in the individual particles at from 5% to  
3 99% by weight.

1           15. A method for preparing a stable, dry powder  
2 insulin composition, said method comprising:  
3           dissolving insulin in an aqueous buffer to form a  
4 solution; and  
5           spray drying the solution to produce substantially  
6 amorphous particles having an average size below 10  $\mu\text{m}$ .

1           16. A method as in claim 15, wherein the insulin is  
2 dissolved in a aqueous buffer together with a pharmaceutical  
3 carrier, wherein a dry powder having insulin present in  
4 individual particles at from 5% to 99% by weight is produced  
5 upon spray drying.

1           17. A method as in claim 16, wherein the  
2 pharmaceutical carrier is a carbohydrate, organic salt, amino  
3 acid, peptide, or protein which produces a powder upon spray  
4 drying.

1           18. A method as in claim 17, wherein the  
2 carbohydrate is selected from the group consisting of  
3 mannitol, raffinose, lactose, malto dextrin and trehalose.

1           19. A method as in claim 17, wherein the organic  
2 salt is selected from the group consisting of sodium citrate,  
3 sodium acetate, and sodium ascorbate.

1           20. An insulin composition for pulmonary delivery,  
2 said composition comprising individual particles which include  
3 insulin present at from 5% to 99% by weight in a  
4 pharmaceutical carrier material and have a size below 10  $\mu\text{m}$ .

1           21. An insulin composition as in claim 20, wherein  
2 the composition is substantially free from penetration  
3 enhancers.

1           22. An insulin composition as in claim 20, wherein  
2 the pharmaceutical carrier material comprises a carbohydrate  
3 selected from the group consisting of mannitol, raffinose,  
4 lactose, malto dextrin, and trehalose.

1           23. An insulin composition as in claim 20, wherein  
2 the pharmaceutical carrier material comprises an organic salt  
3 selected from the group consisting of sodium citrate, sodium  
4 gluconate, and sodium ascorbate.

1           24. An insulin composition produced by the method  
2 of claim 15.

1           25. An insulin composition consisting essentially  
2 of dry powder insulin having an average particle size below  
3 10  $\mu\text{m}$ .